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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,596	01/21/2004	Wilfred Wayne Lautt	14217.1USC1	4255

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EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/761,596

Applicant(s)

LAUTT, WILFRED WAYNE

Examiner

Cybille Delacroix-Muirheid

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13 and 17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

The following is responsive to the request for continued examination and the amendment received Aug. 22, 2005.

Claims 1-10, 14-16 are cancelled. New claim 17 is added. Claims 11-13, 17 are currently pending.

The previous claim rejections under 35 USC 112, first and second paragraph, set forth in paragraphs 1-2 of the office action mailed May 20, 2005 are withdrawn in view of applicant's amendment and the remarks contained therein.

The previous claim rejections under 35 USC 102(b) and (e), set forth in paragraphs 2-5 of the office action mailed Sep. 22, 2004 and maintained in the office action mailed May 20, 2005 are withdrawn in view of applicant's amendment and the remarks contained therein.

Finally, applicant's arguments traversing the previous claim rejection under 35 USC 103(a) set forth on pages 5-6 of the office action mailed Sep. 22, 2004 and maintained in the office action mailed May 20, 2005 have been considered but are moot in view of the following new ground(s) of rejection.

The previous claim rejection under 35 USC 103(a) is therefore withdrawn.

New Ground(s) of Rejection

Claim Rejection(s)—35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 11-13, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al., 6,165,975 and Papandreou et al., 6,171,232 and Salzman et al., 5,958,427 and Klokke-Bethke et al., 5,370,862 and Veronesi et al., 5,580,576 (all references already of record).

Klokke-Bethke et al. disclose pharmaceutical aerosol sprays containing effective amounts of the nitric oxide agonist, nitroglycerin. Please see the abstract; claim 1.

Veronesi et al. disclose pharmaceutically/storage stable, water resistant formulations comprising nicorandil (a nitric oxide agonist) and pharmaceutically acceptable excipients. Please see the abstract; claim 1.

Adams et al. teach pharmaceutical compositions comprising effective amounts of either sodium nitroprusside, 3-morpholinol-synonimine, molsidomine or S-nitroso-N-acetyl penicillamine (SNAP) and a pharmaceutically acceptable carrier. Please see the abstract; col. 7, lines 33-47; col. 15, lines 1-67.

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Papandreou et al. teach that sodium prusside is a generally approved nitric oxide donor pharmaceutical. Furthermore, other known nitric oxide pharmaceuticals include sodium nitrite and the sydnonimines. Please see col. 6, lines 45-55.

Salzman et al. teach pharmaceutical compositions containing effective amounts of nitric oxide donor compounds. Please see the abstract; col. 2-6.

These prior art references do not, however, specifically disclose formulating the compositions into a kit with instructional material that specify for oral administration of the nitric oxide donor and/or nitric oxide agonists compositions.

Yet, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pharmaceutical composition of these references to include a package insert with instructional material for indications and use because the inclusion of package inserts is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art. (Please see *Remington's: the Science and Practice of Pharmacy*, Nineteenth Edition, Vol. 1, page 806).

Moreover, the court in In re Gulack states "where printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability." Please see In re Ngai et al., 70 USPQ2d 1862 (CAFC 2004) (citing In re Gulack, 217 USPQ 401 (CAFC 1983)). In this case, the instructional material is not functionally related to the compositions containing nitric oxide donor and/or nitric oxide agonists because these compositions can function as active, effective drugs even in the absence of the instructional material. Therefore, following the rationale in Ngai and Gulack, one can conclude that the instructional

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material does not patentably distinguish the claimed compositions over the prior art.

Finally, the instructional material for using the nitric oxide donor and/or nitric oxide agonist compounds to ameliorate symptoms of insulin resistance relates to intended use and does not further limit or define the overall pharmaceutical compositions.

Concerning the limitation “structurally modified to preferentially release nitric oxide in the liver”, the Examiner notes that at page 8, lines 10-15 of the specification, the limitation “nitric oxide donors and agonists” is described as encompassing a number of compounds such as SIN-1, SNAP, sodium nitrite and nitroprusside. The Examiner respectfully submits that although the references don’t specifically disclose that the nitric oxide donors or agonists are “structurally adapted to preferentially release nitric oxide in the liver”, the references do disclose compositions containing compounds (nitroglycerin, nicorandil, SNAP, sodium nitroprusside, etc.) that are encompassed by the claims.

Finally with respect to claim 17, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a composition containing a combination of a nitric oxide donor and a nitric oxide agonist because one of ordinary skill in the art would reasonably expect the additive effect of the two compounds to enhance production or release of nitric oxide in a patient in need thereof.

Conclusion


Claims 11-13, 17 are rejected.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybillie Delacroix-Muirheid** whose telephone number is **571-272-0572**. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Christopher Low**, can be reached on **571-272-0951**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM 
Sep. 5, 2005


Cybillie Delacroix-Muirheid
Patent Examiner Group 1600